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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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01/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/758,864	Applicant(s) WONG ET AL.	
	Examiner Brian S. Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-17, 39, 40 and 54-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17, 39, 40 and 54-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114.

2. The examiner for the instant application has changed. The current examiner assigned to this application is Brian-Yong S. Kwon.

Claims 1-12, 14-17, 39-40 and 54-67 are currently pending for prosecution on the merits.

Summary of Action

4. The rejection of claims 1-12, 14-17 and 39-40 and 54-67 under the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of US Patent No. 6465458 is not maintained in light of the approved Terminal Disclaimer filed 08/11/2006.

5. The rejection of claims 1-12, 14-17, 39, 40 and 54-67 under 35 USC 112, first paragraph, is maintained for the reasons of record.

6. Claims 1-12, 14-17, 39, 40 and 54-67 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-12, 14-17, 39, 40 and 54-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating post-herpetic neuralgia, does not reasonably provide enablement for treating (or preventing) “peripheral neuropathy”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The instant specification defines that the terms “treat”, “treatment”, and “treating” refer to “(a) preventing a disease, disorder, or condition from occurring in a human which may be predisposed to the disease, disorder and/or condition....(b) inhibiting the disease, disorder” (page 17, line 28 through page 18, line 6).

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The American Heritage Dictionary (Second College Edition, 1982) defines the term “inhibit” as “restrain or hold back; prevent” and the term “prevent” as “anticipate or counter in advance, to keep from happening”.

The term “peripheral neuropathy” is generally recognized in the art as “a scope of clinical syndromes affecting a variety of peripheral nerve cells and fibers, including motor, sensory and autonomic fibers” (“Peripheral Neuropathy”, Robert W. Shields, Jr., published February 9, 2004, www.clevelandclinicmeded.com), “range from a condition in which there is damage to nerve fibers within the peripheral nervous system to the more traditional distal symmetric polyneuropathy” (“Diagnosis of Peripheral Neuropathies”, Ira Chang, CNI Review, 2002, Vol. 13, Number 2), “a term to describe disorders of your peripheral nervous system” (“Peripheral Neuropathy”, November 1, 2005, MayoClinic.com) and “a wide range of disorders in which the nerves outside of the brain and spinal-cord-peripheral nerves-have been damaged” (“Peripheral Neuropathy”, Julia Barrett, Gale Encyclopedia of Medicine, 1999).

The interpretation of the instant claims (given “broadest reasonable interpretation”) allows for the inclusion of prophylactic utility (prevention, complete cure and eradication or total elimination) and therapeutic treatment of very broad scope of disorders or diseases of the peripheral nervous system characterized by common symptoms of numbness, tingling sensation, a prickling sensation or pain, including Gullain-Barre syndrome, chronic inflammatory demyelinating polyradiculoneuropathy, porphyria, vitamin B12 deficiency, uremia, chronic liver disease, carcinoma (sensory, sensori-motor, late, demyelinating), polycythemia vera, acromegaly, benign monoclonal gammopathy, macroglobulinemia, cryoglobulinemia, Fabry’s disease, Ataxia-

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telangiectasia, sjogren's syndrome, diabetes mellitus, and etc...(that are known to exist today and those that may be discovered in the future) by the administration of said optically pure (S,S) reboxetine, or pharmaceutically acceptable salt thereof to the individual.

With respect to the scope of enablement for prevention of peripheral neuropathy,

It is known today that no medical treatments exist that can cure peripheral neuropathies including diabetic neuropathy and post-herpetic neuralgia available besides a purely symptomatic treatment of the disease or treat the underlying cause ("NINDS Peripheral Neuropathy Information Page", 2006, www.ninds.nih.gov; "Diabetic Neuropathy", Dana L. Rowett, 2004, www.health.yahoo.com; "Post-Herpetic Neuralgia in Older Patients", Bowsher, D., Drugs Aging, abstract, 1994, 5(6):411-8). Thus, it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" or completely cure or eradication effect.

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmacy art is high. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the preventive utility of the instant compounds.

The specification provides assay in vitro and discloses that (S,S) reboxetine exhibits high inhibition selectivity over norepinephrine receptor (Example, particularly Table). In addition, Dr. Ratcliffe's Declaration filed January 17, 2006 shows that the administration (S,S) reboxetine is useful in treating post-herpetic neuralgia. However,

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there is no demonstrated correlation that the tests and results apply to the claimed preventive utility embraced by the instant claims.

Since the efficacy of the claimed compound(s) in preventing the peripheral neuropathy mentioned above cannot be predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

With respect to scope of enablement for "peripheral neuropathy",

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. Nationwide Chem. Corp. v. Wright, 458 F. supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); Aff'd 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. For example, in Ex Parte Sudilovsky, the Court held that Appellant's invention directed to a method for preventing or treating a disease known as tardive dyskinesia using an angiotensin converting enzyme inhibitor involved unpredictable art because it concerned the pharmaceutical activity of the compound. 21 USPQ2d 1702, 1704-5(BDAI 1991); In re Fisher, 427 F.2d 1557, 1562, 29 USPQ, 22 (holding that the physiological activity of

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compositions of adrenocorticotrophic hormones was unpredictable art; In re Wright, 999 F.2d 1577, 1562, 29 USPQ d, 1570, 1513-14 (Fed. Cir. 1993) (holding that the physiological activity of RNA viruses was unpredictable art); Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (BDAI 1987); Ex Parte Singh, 17 USPQ2d 1714, 1715, 1716 (BPAI 1990). Likewise, the physiological or pharmaceutical activity of treating (or preventing) peripheral neuropathy prior to filling of the instant invention was an unpredictable art.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fishcher, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright, 999 F.2d 1562-63, 27 USPQ2d 1575.

At the time of the invention was made, it was generally recognized in the art that not all of antidepressants would work similarly in the treatment of various types of the peripheral neuropathy. For example, the third generation selective reuptake inhibitor such as fluoxetine (see page 3, lines 5-7 of the instant specification) was found ineffective for the treatment of diabetic neuropathy (see "Question and Answer", ARCH FAM MED, Vol. 7, 1998, pp.470-471, particularly column 2, lines 3-25 and lines 50-55). Tricyclic

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antidepressant such as amitriptyline was found ineffective for the treatment of HIV-related peripheral neuropathy (JAMA, November 11, 1998, Vol. 280, No. 18 pp.1590-1595).

Although the specification and Declaration provides the activity of (S,S) reboxetine in inhibiting selectivity (high) on norepinephrine receptor over serotonin receptor and the utility of said (S,S) reboxetine in treating post-herpetic neuralgia, the specification fails to provide sufficient guidance in how to treat (or prevent) very broad scope of diseases or conditions of peripheral nervous system encompassed by the instant invention without undue amount of experimentation. As discussed in preceding comments, in the instant case, only a limited number of example that are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of diseases required. The instant claims read on any disorders or diseases that are affecting a variety of peripheral nerve cells and fibers, including motor, sensory and autonomic fibers, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

As discussed above, considering above factors, especially the “sufficient working examples”, “the level of skill in the art”, “the unpredictability in the pharmaceutical art”, “breadth of the claims” and “the amount of direction or guidance presented”, one of ordinary skill in the art would be burdened with undue “painstaking experimentation study” to practice the invention commensurate in scope with these claims (The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether is required to make/use the instant invention. “the

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test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” In re Wands, 858 F.2d 737, 8 USPQ2d 1404 (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976))).

The examiner acknowledges that the Office does not require the present of (all) working examples to be present in the disclosure of the invention (see MPEP 2164.02). However, given the highly unpredictable state of the art and furthermore, given that the applicant does not provide sufficient guidance or direction as to how to make and use the full scope of the presently claimed invention without undue amount of experimentation, the Office would require appropriate disclosure, in the way of scientifically sound reasoning or the way of concrete examples, as to why the data shown is a reasonably representative and objective showing such that it was commensurate in scope with and, thus, adequately enables, the use of the elected species for the full scope of the presently claimed subject matter. Absent such evidence or reasoning, applicant has failed to obviate the rejection of the instant claims under 35 USC 112, first paragraph (for the lack of scope of enablement).

8. Claims 39, 40 and 54-67 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The present claims are drawn to a method of treating an individual suffering from peripheral neuropathy while diminishing adverse side effects comprising administering a total dose of about 0.1 to about 10 mg/day of an optically pure (S,S) reboxetine, or pharmaceutically acceptable salt thereof to the individual.

The instant specification discloses that the administration of reboxetine can result in undesired side effects associated with drug-drug interactions and in other undesirable effects (e.g., dizziness, insomnia, lightheadedness, changes in blood pressure, sweating, gastrointestinal disturbances, sexual dysfunction in males, certain anticholinergic-like effects (e.g., tachyarrhythmia and urinary retention)) because reboxetine lacks a sufficiently high selectivity for inhibiting norepinephrine reuptake (page 8, lines 1-10).

As discussed above, the instant specification discloses the treatment of peripheral neuropathy by administering said (S,S) reboxetine, wherein said reboxetine causes less adverse effects compared to the racemic mixture of reboxetine or (R,R) reboxetine enantiomer, which meets the written description. However, the specification provides insufficient written description to support the activity of (S,S) reboxetine enantiomer in diminishing adverse side effects caused by the racemic reboxetine or (R,R) reboxetine (or broadly non-selective serotonin reuptake inhibitor alleged by the applicants' representative, Sandip H. Patel, during the telephonic interview conducted on January 04, 2007)) in individual suffering from said peripheral neuropathy encompassed by the instant claims. None of these meet the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

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he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for using it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-12, 14-17, 39, 40 and 54-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding particularly independent claims 1 and 39, the phrase “therapeutically effective” renders the claim indefinite because the claim includes elements not actually disclosed which could mean the administering of the compound is for many medical treatments, thereby rendering the scope of the claim unascertainable. See MPEP 2173.05(d).

The applicant could overcome this rejection by amending “therapeutically effective amount of optically pure (S,S) reboxetine...” to “an optically pure (S,S) reboxetine, or a pharmaceutically acceptable salt thereof, in a therapeutically effective amount to treat...”.

Regarding the independent claim 39, the phrase “while diminishing adverse side effects” in the preamble renders the claim indefinite because the claim is omitting essential step(s) required in “diminishing adverse side effects”.

The interpretation of the instant claims allows for inclusion of the step of administering (S,S) reboxetine to diminish adverse effects caused by reboxetine or (R,R) reboxetine (broadly non-selective serotonin reuptake inhibitor as the applicants’ representative, Sandip H. Patel, alleged during the telephonic interview conducted on January 04, 2007). However, there is no indication in the instant claim that reboxetine or

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(R,R) reboxetine (broadly as non-selective serotonin reuptake inhibitor) must be coadministered with (S,S) reboxetine. Nor the specification provides any supports for the activity of the instant (S,S) reboxetine in diminishing adverse side effects resulted from the reboxetine, (R,R) reboxetine or non-selective serotonin reuptake inhibitor.

Apparently, this inconsistency between the specification disclosure and the claims leads to lack of clarity of the claims as a whole.

Response to Arguments

10. Applicant's arguments and Declaration filed 08/11/06 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that in contrast to the examiner's assertion, the instantly claimed "peripheral neuropathy" is not considered to be a disease of the peripheral nervous system, but rather "a symptom complex".

Applicant asserts that the skilled artisan recognizes that treatment of a symptom complex, such as peripheral neuropathy, may be accomplished by alleviating or otherwise controlling one or more symptoms.

This argument is not found persuasive. Unlike the applicant's argument, there is no indication in the instant claims that the administration of (S,S) reboxetine must essentially reduce or alleviate symptoms of peripheral neuropathy. In other words, the interpretation of instant claims is not limited to the treatment of symptom of peripheral neuropathy as the applicant alleged. If the criticality of the instant invention is based on "a reduction of the symptoms of the disease or disorder" as the applicant alleged, such feature must be appeared in the claims so that the examiner give a preamble patentable

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weight. In absence of such critical element(s) in the claim, the examiner maintains the rejection of the record.

There is preponderous compelling evidences from the state of art (see cited references in PTO-892, U,V,W and X) that “peripheral neuropathy” refers to disorders of peripheral nervous system, not as “symptom complex” as the applicant alleged. Thus, given “broadest reasonable interpretation”, the examiner determines that the instant term “peripheral neuropathy” indeed encompasses very broad scope of disorders or diseases of the peripheral nervous system characterized by common symptoms of numbness, tingling sensation, a prickling sensation or pain, including Gullain-Barre syndrome, chronic inflammatory demyelinating polyradiculoneuropathy, porphyria, vitamin B12 deficiency, uremia, chronic liver disease, carcinoma (sensory, sensori-motor, late, demyelinating), polycythemia vera, acromegaly, benign monoclonal gammopathy, macroglobulinemia, cryoglobulinemia, Fabry’s disease, Ataxia-telangiectasia, sjogren’s syndrome, diabetes mellitus, and etc...

Applicant’s argument in the response takes the position that as evidenced by Americ declaration, Ratcliffe Declaration and Ratcliffe and Stoker Declaration, the skilled artisan would have readily understood that the invention could be practiced in scope encompassed by the claims.

This argument is not found persuasive. As (also) acknowledged by the applicant (page 5, lines 25-35 and page 8, last paragraph to bridging paragraph in page 9), post herpetic neuralgia (PHN) or diabetic peripheral neuropathy (DPN) is known to be a representative disorder of the peripheral neuropathic pain, not “peripheral neuropathy”.

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Peripheral neuropathic pain is a subset of "peripheral neuropathy" and is not interchangeable with the term "peripheral neuropathy".

Similar to the Stoker Declaration, antidepressants (e.g., NMDA antagonist such as pregabalin and gabapentin, tricyclic antidepressant such as amitriptyline and imipramine, MAO inhibitor, selective reuptake inhibitors) have been clinically utilized for the treatment of controlling particular symptom of peripheral neuropathy, pain. For example, use of TCA such as amitriptyline or NMDA antagonist such as pregabalin (Lyrice) and gabapentin (Neurontin) for the treatment of DPN or PHN are well established in the art. However, not all of the antidepressants are known to provide similar activity for the treatment of various types of the peripheral neuropathy. For example, the third generation selective reuptake inhibitor such as fluoxetine, which falls into same category as the instant reboxetine (see page 3, lines 5-7 of the instant specification), was found ineffective for the treatment of diabetic neuropathy (see "Question and Answer", ARCH FAM MED, Vol. 7, 1998, pp.470-471, particularly column 2, lines 3-25 and lines 50-55). Tricyclic antidepressant such as amitriptyline was found ineffective for the treatment of HIV-related peripheral neuropathy (JAMA, November 11, 1998, Vol. 280, No. 18 pp.1590-1595).

Considering high unpredictability of physiological activity of antidepressants in the treatment of "peripheral neuropathy" and absence of sufficient guidance in the instant specification in how to treat (or prevent) very broad scope of diseases or conditions of peripheral nervous system encompassed by the instant invention, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to practice the invention commensurate in scope with these claims. As discussed above, the instant

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invention necessitates an exhaustive search for the embodiments suitable to practice the claimed invention, without undue amount of experimentation.

Conclusion

11. No Claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614

